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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,888

Applicant(s)

BARROWS, THOMAS H.

Examiner

Isis Ghali

Art Unit

1615

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 23-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's IDS, filed 01/08/2002; and election, filed 10/29/2002.

Response to Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-22, in Paper No. 5, is acknowledged. The traversal is on the ground(s) that the five groups of the claims are directed to different embodiments of the same invention and not to distinct inventions, and the search and examination of the entire application can be made without serious burden on the examiner. This is not found persuasive because the groups are directed to distinct invention each group can sustain separate patent within the art because Group II requires semi-rigid backing, Group III requires three-dimensional matrix, Group IV requires osteoblats, and Group V requires reservoir and wire core. Under PCT article 13, applicants are entitled to examination of a single invention. The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, no reason to expect the search to be un-extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to

obtain a patent for a single invention. In the opinion of the examiner the applicants present five distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 23-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the term "means" renders the claims indefinite since it is not clear what applicant intended to cover by the recitation of the "filamentary means".

Regarding claim 4, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 4 recites the broad recitation protein, and the claim also recites collagen, gelatin and albumin, which is the narrower statement of the range/limitation.

Regarding claim 15, the claim recites the limitation "open pores" in claim 13. There is insufficient antecedent basis for this limitation in the claim.

In claims 14 and 15, the expression "large enough" renders the claims indefinite because this limitation relates the size of the claimed pores to the properties of other molecules without guidance to the size of the other molecules.

Regarding claims 17-22, the claims are method claims, and improperly depending on claim 15, which is a product claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1-5, 11-14, 16, 17, 20, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,486,593 ('593).

US '593 disclosed bioabsorbable and/or biodegradable solid fiber coated with polymer to form core-sheath structure (col.5, lines 1-5, 15-18; col.7, lines 7-12). The fibers may be used in monofilament form coated with other polymers (col.7, lines 28, 36). The polymers used for the invention (for both core and sheath) include d,l lactide, dioxanones, and anhydrides (col.16, lines 10-40). The polymers contain drugs such as growth factor and can be coated on the porous layer (col.19, lines 1, 10-15, 27-30). The fibers can also comprise titanium, metal alloys such as chromium, cobalt, and molybdenum (col.19, lines 40-45). The fibers of the invention are formed in solid form by

melt extrusion, and then coated with polymer layer by solution dipping (col.5, 11-48; col.7, lines 20-27). The pores are formed by using chemical foaming agents (col.7, lines 21-26). The limitations of the above claims are met by the reference.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '593 in view of US 6,027,744 ('744) as applied to claims 6,7 and further, may or not in view of US 4,104,195 ('195) as applied to claims 18-19.

US '593 discloses bioabsorbable and/or biodegradable solid fiber coated with polymer to form core-sheath structure (col.5, lines 1-5, 15-18; col.7, lines 7-12). The fibers may be used in monofilament form coated with other polymers (col.7, lines 28, 36). The polymers used for the invention (for both core and sheath) include d,l lactide, dioxanones, and anhydrides (col.16, lines 10-40). The polymers contain drugs such as growth factor and can be coated on the porous layer (col.19, lines 1, 10-15, 27-30). The fibers can also comprise titanium, metal alloys such as chromium, cobalt, and molybdenum (col.19, lines 40-45). The fibers of the invention are formed in solid form by melt extrusion, and then coated with polymer layer by solution dipping (col.5, 11-48;

col.7, lines 20-27). The pores are formed by using chemical foaming agents (col.7, lines 21-26).

US '593 does not teach the active agent as hair follicles, or as genetically engineered or encapsulated cells. The reference does not teach the particular foam forming agents.

US '744 disclosed living hair follicles incorporated in a biocompatible support structure (abstract; col.2, lines 65-66; col.3, lines 20-28). The support structure is rigid biodegradable and biocompatible includes ceramic or metal structure (col.2, lines 1-12, 46-47; col.16, lines 44-46). The support structure can be a polymer fibers coated by polyglycolic acid (col.6, lines 1- 37). Further the implant comprises nutrients and growth factors (col.1, lines 59-62; col.5, lines 60-67).

US '195 teaches foam forming agents that does not give off any corrosive, discoloring, unpleasant smelling or toxic decomposition products (col.1, lines 52-57). The foam forming agents disclosed by the reference include azodicarbonamide and urea dicarboxylic acid anhydride (col.2, lines 47-60).

It is well known in the implanting art to use genetically engineered cells and cell signaling molecule. However, applicants did not show superior and unexpected results in using the genetically engineered cells or the cell signaling molecules in particular.

It is also within the skill in the art to select the foaming material according to specific need, especially applicants provided no unexpected result to show the criticality of the azodicarbonamide and urea dicarboxylic acid anhydride as foaming agents.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide biocompatible biodegradable filament comprising core-sheath structure as disclosed by US '593, and add the hair follicles as an active agent into the filaments, as taught by US '744, motivated by the teaching of US '744 that the biodegradable polymer allows nutrients to diffuse to the cell and promote cell growth and proliferation, and replace the chemical foaming agent disclosed by US '593 by the azodicarbonamide or urea dicarboxylic acid anhydride as disclosed by US '195 motivated by the teaching of US '195 that these agents do not give off any corrosive, discoloring, unpleasant smelling or toxic decomposition products, with reasonable expectation of success of the delivered filaments to implant hair follicles into a needy host.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,599,552 and US 5,847,012 both disclosed biodegradable foam implant that can have a porous outer layer and deliver active agents and cells.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615


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